

Date: 8 August 2022

Re: Freedom of Information Request
Ref: 244-2022

Thank you for your email dated the 12th July 2022, requesting information in relation to head/neck and urothelial cancer.

The information you require is as follows:

1. How many patients have been treated in the past 3 months for head and neck cancer (squamous cell carcinoma) with the following agents:

Carboplatin (monotherapy or in combination with 5-FU)	11
Cisplatin (monotherapy or in combination with 5-FU)	13
Cetuximab with/without chemotherapy	<5
Cetuximab with radiotherapy	<5
Pembrolizumab monotherapy	20
Pembrolizumab with chemotherapy	0
Nivolumab	9
Docetaxel (monotherapy or in combination with 5-FU)	3
Fluorouracil (5FU)	0
Radiotherapy only	0
Other:	
Cisplatin + Docetaxel +Fluorouracil	4
Cisplatin + Radiotherapy	1
Cisplatin with Radiotherapy	44
Denosumab	3
Durvalumab	3
Paclitaxel	3
TG4050 (Transgene Trial)	6

2. For the patients treated in the past 3 months for head and neck cancer (squamous cell carcinoma) with the therapies listed in the first question, please provide:

Total number of head and neck cancer patients	135
Number of locally advanced head and neck cancer patients	71
Number of unresectable recurrent and/or metastatic head and neck cancer patients	We are not able to identify of the recurrent is resectable or not

3. How many Urothelial cancer patients have been treated in the past 3 months with the following agents:

Avelumab	0
Atezolizumab	0
Carboplatin with Gemcitabine	0
Carboplatin single or in any other combination	0
Cisplatin with Gemcitabine	0
Cisplatin single or in any other combination	0
Nivolumab	0
Pembrolizumab	0
Any other regimen including Paclitaxel	0
Any other chemotherapy regimen	0
Other active systemic anti-cancer therapy [please state]	0
Palliative care only	0

4. Does your trust participate in any ongoing clinical trials for the treatment of head and neck cancer? If so, can you please provide the name of each trial along with the number of patients taking part?

Project Acronym	Project Full title	Project phase	Recruited
SMARTPLUS-301 (TrilynX)	SMARTPLUS-301: A randomized, double-blind placebo-controlled, phase III study of Debio 1143 in combination with standard platinum-based concomitant fractionation chemoradiation therapy (CRT) in high-risk patients with inoperable locally advanced squamous cell carcinoma of the head and neck.		0
REPLIMUNE	An Open-Label, Multicenter, Phase 1/2 Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors	Phase I/II	10

Transgene	A randomized phase I trial in patients with newly-diagnosed, locoregionally advanced, HPV-negative, squamous cell carcinoma of the head and neck (SCCHN) evaluating a mutanome-directed immunotherapy initiated at completion of primary treatment or at time of recurrence.	Phase I	0** (see note)	We have 6 patients on this trial. We lead the UK arm for the non-surgical anti-cancer therapy for this trial. The pathway for this trial means patients are recruited via surgical teams at other sites and referred to us for the trial.
BNT113	An open label Phase II randomized trial of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable recurrent, or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) which is positive for human papilloma virus 16 (HPV16+) and expresses PD-L1.	Phase II	0	
MOAT Study	A multicentre, open-label, non-randomized, phase Ib, neoadjuvant study of intravenous dosing of NG-641, an oncolytic adenoviral vector expressing a fibroblast activation protein-directed bi-specific T-cell activator antibody fragment (FAP-TAc) and an immune enhancer module (CXCL9/CXCL10/interferon alpha2), as monotherapy or in combination with pembrolizumab in patients with surgically resectable squamous cell carcinoma of the head and neck (Mode Of Action Transgene study- MOAT)	Phase I	<5	
PATHOS	A Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	Phase II/III	62	
POPPY	A phase II trial to assess the efficacy and safety profile of pembrolizumab in patients with performance status 2 with recurrent or metastatic squamous cell carcinoma of the head and neck	Phase II	<5	
Best-Of	Phase III study assessing the 'Best-Of' radiotherapy compared to the 'Best-Of' surgery (trans-oral surgery (TOS) in patients with T1-T2, N0 oropharyngeal carcinoma	Not Applicable	<5	This is a trial comparing different treatment options and is worked in tandem with surgical teams at a partner Trust. We support in providing radiotherapy.

Where a dataset includes a small number of patients, and the content of the dataset is deemed to be of sufficient risk for re-identification of the

patient(s) when combined with another dataset, the number has been stated as <5.

Should you require any further information please do not hesitate to contact me on the email address provided below.

Please remember to quote the reference number above in any future communications.

If you are dissatisfied with the handling of your request, you have the right to ask for this to be investigated internally.

If you are dissatisfied with the information you have received, you have the right to ask for an internal review.

Both processes will be handled in accordance with our Trust's Freedom of Information Policy and the Freedom of Information Act 2000.

Internal investigation and internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to: Freedom of Information Review, The Clatterbridge Cancer Centre NHS Foundation Trust, Clatterbridge Road, Bebington, Wirral, CH63 4JY

If you are not satisfied with the outcome of the internal investigation/review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

In order for us to ensure customer satisfaction and to monitor compliance with the Freedom of Information Act 2000, we would be grateful if you could take a couple of minutes to complete a short feedback form via the link below:

<https://forms.office.com/r/eLzHXi49Ea>



Kind Regards,

The Information Governance Team
Contact Email: ccf-tr.foi@nhs.net